UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,504	07/25/2003	Clark C. Davis	1001.1869101	1503

28075 7590 05/21/2008
CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
05/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/604,504	DAVIS ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,25,27,53-59,78 and 81-87* is/are pending in the application.

4a) Of the above claim(s) *5,9,11,12,15-17,21,54,56 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,10,13,14,18-20,25,27,53,55,58,59,78 and 81-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4, 6-8, 10, 14, 19, 20, 25, 27, 53, 55, 58, 59, 78 and 81-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) in view of Shiber (5,135,531), as evidenced by Hernandez et al (5,396,212).

Jacobsen et al disclose a coronary guidewire system and further disclose an elongate body having a proximal end, a distal end and a longitudinal axis extending at least from the proximal end to the distal end; a helical coil formed of radiopaque wire (see Figures 15-17; Column 11, lines 66-67; and Column 12, lines 1-5); the body comprising a tubular member (514) having a plurality of slots configured to make the tubular member (514) more flexible in bending; the first coil located at or near the distal end, the first coil substantially comprising a substantially radiopaque material (see Figures 15-17; Column 11, lines 66-67; and Column 12, lines 1-11); a core wire (501), at least part of the core wire being located inside the tubular member (514), at least a portion of the core wire (501) being located inside the first coil (see Figures 15-17); the medical device is a guidewire (see Column 2, lines 39-42); the core wire (501) being attached with a joint to the first tubular member (514) at least at the proximal end, the joint comprising a first coil circumscribing the core wire (501), the first coil being at least partially inside the first tubular member (514), and the joint comprises at least one of

solder and adhesive (see Column 12, lines 9-34); the core wire (501) being metal and the first coil is metal, the joint comprising solder attaching the first coil to the core wire (501) and adhesive attaching at least one of the first coil, the core wire and the solder to the first tubular member (514) (see Column 12, lines 9-34); the tubular member (514) comprising a plurality of slots formed in the tubular member, at least a plurality of slots being substantially perpendicular to the axis, the slots being formed in a plurality of groups, and at least a plurality of groups comprising a plurality of slots at substantially the same location along the axis (see Figure 18); the core wire (501) having a tapered portion, the joint being located at least partially within the tapered portion (see Figures 14 and 18); the core wire (501) further being attached to the first tubular member (514) at the distal end of the tubular member (514) (SEE Column 12, lines 9-34); the core wire (501) further being attached to the tubular member (514) at least one location intermediate (518) the proximal end and the distal end (see Column 12, lines 9-11); the core wire (501) comprising an abrupt change in diameter between the proximal end and the distal end (see Figure 14); radiopaque material inside the tubular member (514), at or adjacent to the distal end of the tubular member (514) (see Figure 18; Column 11, lines 66-67; and Column 12, lines 1-11); the core wire (501) being attached to the tubular member (514) at the distal tip (520) of the core wire (501); and the core wire (501) having at least one abrupt change in cross-sectional dimension, the abrupt change being at or adjacent to the joint (see Figures 14-18).

Jacobsen et al, however fail to disclose the coil being formed from a wire having a substantially non-circular cross section, the cross section having a greater dimension

in the radial direction than in the axial direction, wherein prior to winding, the wire has two substantially flat opposite non-parallel sides that are out of parallel by an angle, and after winding into the coil, the sides are substantially parallel.

Shiber discloses a guided atherectomy system and further discloses the coil being formed from a wire having a substantially non-circular cross section, the cross section having a greater dimension in the radial direction than in the axial direction, and after winding into the coil, the sides are substantially parallel. See Figure 11; and Column 6, lines 45-56.

One of ordinary skill in the art would recognize Shiber implicitly teaches a coil that is created from a trapezoidal cross-sectioned wire and when the coil is formed, the trapezoidal shape becomes a rectangular cross section. In order to obtain the rectangular cross section as taught by Shiber, the wire would have to initially be of a trapezoidal shape before being formed into the coil, because if the wire was initially of a rectangular cross section, the formed coil would be formed into a trapezoidal cross section due to the increase of material on the inside of the formed coil. Hernandez et al discloses a means for winding transformer wire and further discloses the fact that a wire having a rectangular cross-section prior to bending about a radius would become a wire with a trapezoidal cross-section after bending about a radius. See Column 2, lines 53-63 of Hernandez et al. Therefore, Shiber implicitly discloses the use of a trapezoidal shaped flat stock prior to winding into a coil to form the shown rectangular cross-section.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guidewire coil of Jacobsen et al to include the use of a non-circular cross section, as per the teachings of Shiber, since the substitution of a non-circular cross-section coil in the place of a circular cross-section coil would provide the predictable result of being able to navigate a guidewire through the vasculature of the patient.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) and Shiber (5,135,531), as evidenced by Hernandez et al (5,396,212) as applied to claim 7 above, and further in view of Lui (2002/0010475 A1).

Jacobsen et al and Shiber, as discussed above, disclose a guidewire means but fail to disclose the coil formed from wire having a thickness, the first coil having at least a portion of its length with a pitch of at least 1.5 times the wire thickness.

Lui discloses a means for removing an implanted lead from tissue and further disclose the coil formed from wire having a thickness, the first coil having at least a portion of its length with a pitch of at least 1.5 times the wire thickness. See Paragraph 0126.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pitch of the coil of Jacobsen et al and Shiber to be at least 1.5 times the wire thickness, as per the teachings of Lui, since it is well known in the art to utilize certain pitches within the coil to obtain a required flexibility.

4. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) and Shiber (5,135,531), as evidenced by Hernandez et al

(5,396,212) as applied to claim 7 above, and further in view of Levine et al (2003/0009157 A1).

Jacobsen et al and Shiber, as discussed above, disclose a guidewire means, but fail to disclose the tubular member having a chamfer at the proximal end.

Levine et al disclose a flexible flow apparatus and further disclose the tubular member having a chamfer at the proximal end. See Paragraph 0153.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Jacobsen et al and Shiber to include the tube having a chamfer at the proximal end, as per the teachings of Levine et al, since it would provide a means of securing the tube to the core and coil.

Response to Arguments

5. Applicant's arguments filed February 28, 2008 have been fully considered but they are not persuasive.

The Applicants argue Jacobsen et al, Shiber, as evidenced by Hernandez et al, used in the rejection of claims 1-4, 6-8, 10, 14, 19, 20, 25, 27, 53, 55, 58, 59, 78 and 81-87 lack an adequately articulated reason or motivation to combine the prior art to meet the current claims. The Examiner respectfully disagrees. Jacobsen et al clearly disclose the use of a guidewire with a circular cross-section distal coil. Shiber clearly disclose another intravascular medical device that has a rectangular cross-sectional distal coil. KSR v. Teleflex allows for the simple substitution of one known element for another to obtain predictable results. In this instance, the circular cross-sectional coil of Jacobsen

et al is being substituted for that of the rectangular cross-sectional coil of Shiber. The substitution of the rectangular cross-sectional coil of Shiber in the place of the circular cross-sectional coil of Jacobsen et al would still provide a guidewire that is capable of navigating the patient's vasculature, therefore yielding a predictable result. The Applicants further argue that the coil of Shiber would not improve the guidewire of Jacobsen et al. The substitution of the coil of Jacobsen et al with that of the coil of Shiber, merely shows that distal coils on intravascular devices can comprise different cross-sections, and still operate as an intravascular device.

In response to applicant's argument that Shiber is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Shiber provides the teaching of another intravascular device with a distal coil.

Regarding Claims 25, 27 and 82-84, the Applicants argue the proximal end (of the tubular member) abuts an abrupt change in cross-sectional dimension (of the core wire), and Jacobsen et al fail to teach the claimed limitation. Jacobsen et al, in Figures 14 and 18 show a guidewire core in Figure 14, and the finished guidewire in Figure 18. As can be seen in Figure 14, there is an abrupt change in cross-sectional dimension between elements 524 and 530. Then Figure 18 shows the tubular member 514 over the location of the abrupt change between elements 524 and 530. Furthermore, in Column 12, lines 25-30 of Jacobsen et al, the use of an adhesive to join the tubular

member 514 to the core is disclosed. Per the definition of "abut" in Merriam-Webster Online Dictionary, "abut" is defined as "to terminate at a point of contact". The glue joint at the proximal end of the tubular member 514 is the location where the tubular member 514 abuts the core at the abrupt change between elements 514 and 530.

Per the reasons set forth above, the prior art rejection of the currently pending claims is being maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Patent Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736